Therapeutics Healthcare Innovation Cycle

Solution Name: _____ **Status:** ☐ Not Done ☐ + Partial ☐ √ Completed **Date**: _____

Maturity Level	Clinical/Workflow	Market/Business	Regulatory	Technology
1. Need Insights into unmet medical needs and available solutions	☐ Unmet need statement. ☐ Disease state characterized ☐ Disease pathway identified and described	☐ Deficiency in existing solutions identified ☐ Market Assessment/Initial description of target population and its biological characteristics	☐ Regulatory familiarization	☐ Biological Mechanism of action identified ☐ Approaches for pharmacological identified ☐ Initial patent landscape reviewed
2. Idea Potential solution to unmet need described, evaluated and selected	☐ Feedback from 5+ Clinical Stakeholders ☐ Interventions based on biological pathways proposed ☐ Potential use cases developed ☐ Proposed patient population (SOP) defined including genetic or other bio markers (biochemical, cellular, imaging/digital/electrophysiological) if possible	☐ Competitive landscape identified (academic, in pre-clinical/clinical development/commercial) ☐ Envisioned Value Proposition ☐ Draft Target Product Profile (TPP) ☐ Key stakeholders identified ☐ Market Map and Segmentation	☐ Clinical trials in the indication identified for reference trial design and timelines (ie. clinicaltrials.gov landscape) ☐ For rare disease, paediatric or cell & gene therapy: Consulted the regulatory roadmap pathways if applicable and familiarized with alternative pathways	☐ Mechanism of action of target group elucidated in vitro ☐ Compound starting point, screening and selection scheme planning done ☐ Hypotheses (Bio and Pharma) and Experimental Design ☐ Institutional “Idea” (IP) disclosure ☐ Translational models (patient sample based or in-vivo) identified
3. Proof of Concept (PoC) Key component concepts validated in models and value proposition tested	☐ Feedback from Clinical Stakeholders in 5+ settings ☐ Mechanistic and therapeutic hypothesis validated in genetic/metabolic models and/or patient derived cells ☐ Target outcomes ☐ For repurposed products: Proof of concept in relevant in vivo model obtained with repurposed candidate	☐ Scientific Advisory Board recruited ☐ Preliminary Path-to-Payment Plan ☐ Preliminary Value Proposition ☐ Stakeholder Map ☐ Competing Solutions Characterized ☐ Business Protection Model	☐ Preliminary regulatory classification ☐ Preliminary indications for use	☐ Prior art and Freedom to Operate assessment ☐ IP strategy defined. ☐ Updated institutional IP disclosure ☐ Initial hits/compound candidates synthesized and evaluated ☐ Initial pharmacology analysis – efficacy, safety, PK and bioavailability in rodent/relevant animal model (if applicable) ☐ Manufacturing roadmap and costing estimates defined

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4. Proof of Feasibility (PoF) Feasibility of whole solution demonstrated in models and in feedback from stakeholders	☐ Updated need description with confirmation of target patient population ☐ Proposed treatment scheme developed (preventive/therapeutic acute/chronic etc.) ☐ Clinical KOLs committed to participate in clinical trials ☐ Feedback from Users in 20+ Settings ☐ Draft clinical development plan completed (Incl. target population and line of care and target regimen)	☐ Business Advisory Board ☐ Deal and market benchmark cases identified ☐ Preliminary business model ☐ Target Product Profile (TPP) refined ☐ Secure Access to Core IP ☐ Development Plan ☐ Feedback from 5+ Economic Buyers ☐ Collection of economic data compared to SoC started	☐ Drafted essential requirements checklist ☐ Institutional approval request(s) ☐ Submission pathway defined and validated by a regulatory body (scientific advice in EMA or official pre-IND meeting for FDA)	☐ Feasibility proven in essential experiment – safety, bioavailability, PK-PD. For gene therapy product: biodistribution data in big animal (monkey, pig) provided ☐ Composition of matter IP filed - IP search report is promising ☐ Key In-sourcing/licensing plans ☐ Manufacturing partners and plans identified ☐ Hit/lead compounds efficacy and potency in animal model or patient derived model validated
5. Proof of Value (PoV) The potential of the solution to work and create value for all stakeholders is demonstrated	☐ Medical advisory board recruited ☐ Clinical protocol completed ☐ Clinical trial endpoints defined ☐ Peer reviewed publication(s) accepted (preclinical, consider strategic perspective) ☐ Feedback from 50+ Clinical Stakeholders	☐ Key management team committed ☐ Investor ready business plan ☐ Feedback from 10+ Economic Buyers ☐ Initial Seed investment ☐ Key Relationships (w/CRO) Formalized ☐ Incorporation and Founders Agreement ☐ Collection of economic data compared to SoC completed ☐ Communication & public dissemination plan established	☐ Application to Regulatory Authority Submitted ☐ Submission data package defined - Essential Requirements checklist ☐ IND/CTA meeting scheduled/performed ☐ Clinical Investigation approval(s) achieved (Ethical committees/IRBs)	☐ Minimum viable product (MVP) ready – clinical lead optimized ☐ CMC development started in parallel to IND-enabling safety tox preclinical package ☐ Full IP application – freedom to operate positive opinion ☐ Key In-Sourcing Requirements Committed
6. Initial Clinical Trials (ICT Regulated production of prototypes and collection of clinical and economic data	☐ Endpoints Successfully achieved in clinical safety/efficacy trials (Phase 1/2 clinical trials)	☐ Feedback from 20+ Economic Buyers ☐ Validated Quantification ☐ 1st Institutional investment	☐ Pre-submission filed. ☐ Scientific review / FDA consultation to validate phase II design	☐ cGMPs Compliant Manufacturing Process ☐ Long term safety studies if appliable

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7. Validation of Solution (VoS) The solution is shown to be effective and its value to all stakeholders is validated	☐ Endpoints Successfully achieved in clinical efficacy trials (Phase 2a/2b) ☐ Preparation of Phase 3 clinical studies ☐ Peer reviewed publication(s) accepted - clinical ☐ Biomarker /companion diagnostic validated (if applicable)	☐ Partnering MOUs in place ☐ 2nd Round of Institutional Investment ☐ Purchasing Intent From 10+ Buyers	☐ Submission of Technical File to Regulatory Body ☐ Proactive scientific advice or consultation to validate phase III strategy	☐ Pharmaceutical development (final commercial formulation) completed ☐ cGMPs Compliant Manufacturing Process ☐ Long term safety studies
8. Approval & Launch (A&L) Institutional and regulatory approval received and sales launch	☐ Specialty medical groups review in place ☐ Endpoints successfully achieved in Phase 3 clinical studies ☐ Post marketing trial initiated ☐ Training Materials & Support Established	☐ Initial sales achieved ☐ Regionalization plans	☐ Registration approval and listing ☐ CMS/Public Coverage and CPT/DRG code determination obtained	☐ IP Update ☐ Finalized cGMP Production Environment ☐ Three manufacturing batches validated ☐ Alternative manufacturers identified
9. Clinical Use (Use) The solution is used successfully in day-to- day clinical practice	☐ Included in practice guidelines ☐ Additional data published in peer reviewed journals	☐ Profitable sales achieved ramp-up ☐ New markets launched	☐ Monitoring/ inspections	☐ Key patents issued. ☐ Improvement plan ☐ Alternative manufacturing sites validated
10. Standard of Care (SoC) The solution is recognised as the standard of care	☐ Recommended practice by medical specialty	☐ Dominant market share status ☐ Operating margin profile achieved ☐ Health Economics Study	☐ Post market monitoring	☐ Component Obsolescence Plan ☐ Patent Lifecycle Management

Key:

- Patient Population (SOP) - Standard operating procedures
- KOL- Key Opinion Leader
- HED - Human Equivalent Dose
- PK/PD Modeling - pharmacokinetic/pharmacodynamic modeling
- CRO - Contract research organization
- CMC - Chemistry, manufacturing, and control
- PCT - Patent Cooperation Treaty
- IRB - Institutional Review Board
- CTA - Clinical Trial Application
- IND - Investigational New Drug
- CMS - Centers for Medicare & Medicaid Services
- CPT- Current Procedural Terminology
- DRG - Diagnosis-related group